

Charter for the U.S. Nuclear Regulatory Commission/Agreement State Working Group to Develop Part 35 Training and Experience Implementation Guidance

PURPOSE

The purpose of the Charter is to establish a Working Group (WG) to develop implementation guidance to clarify expectations on how to fulfill training and experience (T&E) requirements and clarify the roles and responsibilities of persons subject to T&E requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, Medical Use of Byproduct Material.

OBJECTIVES

The Working Group's (WG) objective is to develop a guidance document for public comment to address expectations on how individuals who aim to request authorized individual approval on NRC licenses that authorize the medical use of byproduct material can fulfill T&E requirements in 10 CFR Part 35.

BACKGROUND

The NRC's regulations require that individuals complete T&E criteria to be authorized for the medical use of byproduct material and to independently fulfill the radiation safety-related duties of authorized user (AU)¹, authorized medical physicist (AMP), authorized nuclear pharmacist (ANP), and radiation safety officer (RSO). The current regulatory T&E criteria require a defined number of training hours and work experience, including case work, for the range of medical modalities. Certain individuals responsible for the radiation safety program at a licensed facility must have adequate T&E and are subject to T&E requirements in 10 CFR Part 35.

NRC Pathways to Satisfy T&E Requirements in 10 CFR Part 35

The NRC has three pathways by which individuals can be authorized for satisfying the T&E requirements in 10 CFR Part 35:

1. Approval of an individual who is certified by a medical specialty board that has a certification process recognized by the NRC or an Agreement State as meeting the NRC's requirements for T&E, also known as the "board certification pathway;"
2. Approval based on an evaluation of an individual's T&E—completion of classroom and laboratory training and supervised work experience, plus preceptor attestation, also known as the "alternate pathway;" and
3. Approval based on confirmation that an individual is identified on an NRC or Agreement State license for equivalent types of use.

¹ Successful completion of the T&E requirements to become an AU does not reflect on a physician's medical competency related to the administration of byproduct material for medical purposes. An individual's status as an AU means that the individual has met the requirements to handle byproduct material safely.

In 2002 ([67 FR 20249](#)), the NRC amended its regulations for medical use of byproduct material to include a pathway (#2 above) to approve individuals who are not board certified, by specifying the total number of hours of T&E needed to become an AU, AMP, ANP, or RSO. In the final rule, the NRC also added a certification process for medical specialty boards, whereby the NRC or Agreement States can recognize a board if its certification process requires that an individual meet all the requirements listed in the alternate T&E pathway in Subparts B and D through H. To be board certified, an individual must complete the required hours of T&E on specific radiation safety topics, acquire sufficient relevant work experience (including completion of sufficient casework), and obtain a signed preceptor attestation. Having equivalent certification processes ensures that individuals who follow either the board certification pathway or the alternate T&E pathway will meet the same requirements to obtain authorized status. The requirements for the board certification and some alternate T&E pathways were subsequently revised in 2005 ([70 FR 16335](#)).

In 2018 ([83 FR 33046](#)), the NRC amended its preceptor attestation requirements in accordance with the NRC staff's recommendations in SECY-08-0179 ([ML083170176](#)), as follows:

1. Eliminate the attestation requirement for the board certification pathway;
2. Retain the attestation requirement for the alternate T&E pathway; and
3. Accept attestations from residency program directors, as long as at least one member of the residency program faculty is an authorized individual in the same category as the applicant seeking authorized status.

In this rulemaking, the NRC also amended 10 CFR Part 35 to allow a licensee to appoint a qualified individual with expertise in certain uses of byproduct material to serve as an associate RSO (ARSO). In addition, 10 CFR Part 35 was further modified to allow an AU, AMP, or ANP listed on a medical use license to serve as an RSO or ARSO. These changes would have increased the number of individuals available to serve as RSOs or ARSOs as well as potentially increase the number of persons available to serve as preceptors for persons seeking to be authorized as RSOs or ARSOs.

T&E Evaluation and 2020 Notation Vote Paper

In 2017, the Commission directed the staff in SRM-M17087 ([ML17229B284](#)) to evaluate whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals; how those categories should be determined (such as by risks posed by groups of radionuclides or by delivery method); what the appropriate T&E requirements would be for each category; and whether those requirements should be based on hours of T&E or focused more on competency. In response to the SRM, the staff conducted an evaluation and documented its initial results and next steps in SECY-18-0084 ([ML18135A276](#)). In SECY-18-0084, the staff concluded that it may be feasible to establish tailored T&E requirements for different categories of radiopharmaceuticals and to create a means of authorizing the administration of these categories (i.e., a limited AU status); however, more extensive outreach with the medical community was needed to move forward with these efforts.

The staff conducted additional outreach and in January 2020 issued SECY-20-0005 ([ML19217A318](#)), which documented stakeholder feedback and the staff's evaluation of the NRC's T&E requirements and provided a rulemaking plan specifically for T&E requirements applicable to unsealed byproduct material. In this Notation Vote paper, the NRC staff

recommended that the Commission revise the T&E requirements in 10 CFR Part 35, Subparts D and E to include the board certification² pathway as the only pathway for a physician to become an AU and to remove the alternate T&E pathway some years after implementation of the rule.

In SRM-SECY-20-0005 ([ML22027A519](#)), the Commission directed staff to maintain the status quo with respect to T&E requirements applicable to the medical use of unsealed byproduct material. However, the Commission further directed the staff to develop implementation guidance to clarify how individuals can fulfill T&E requirements and clarify the roles and responsibilities of persons subject to these requirements; to reevaluate the full complement of T&E requirements for emerging medical technologies; and to conduct a review of NRC-recognized medical specialty boards. The NRC staff completed the review of NRC-recognized medical specialty boards in July 2022 (see STC-22-048, Notification of Issuance of Medical Specialty Board Evaluation; [ML22215A094](#)) and will evaluate T&E requirements for emerging medical technologies during the rulemaking for rubidium-82 generators and emerging medical technologies.

Request from the American Board of Radiology to Cease NRC Recognition

In April 2022, the American Board of Radiology (ABR) notified the NRC of their intent to cease the NRC recognition of all their board certification processes after December 31, 2023 ([ML22091A272](#)). The NRC currently recognizes six ABR certification processes for AUs, AMPs, and RSOs. Internal and external stakeholders have expressed the need for additional guidance on how individuals who previously relied on ABR certification may, after December 31, 2023, fulfill requirements under the T&E pathway to become AUs, AMPs, or RSOs.

Need for Working Group

The T&E requirements for individuals who use byproduct material for medical purposes are necessary to ensure the safe and secure use of these materials. These requirements have evolved over the years in response to changes in medical practice, and to ensure that access to patient care is not affected by changes in the medical arena. Guidance on the information needed to be submitted to NRC and Agreement States to comply with T&E requirements exists in NUREG-1556, Volume 9, Revision 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses, Final Report" ([ML19256C219](#)). This guidance is periodically updated concurrent with any regulatory changes. However, in the nearer term and given the types of questions that NRC and Agreement State staff routinely receive regarding T&E requirements, the NRC staff has determined that supplemental guidance would benefit individuals applying for authorized status. Given the considerations above, the NRC is forming a joint NRC/Organization of Agreement State (OAS) WG to develop T&E implementation guidance in accordance with SRM-SECY-20-0005.

MEMBERSHIP

The WG is sponsored by the NRC's Division of Materials Safety, Security, State, and Tribal Programs (MSST) within the Office of Nuclear Materials Safety and Safeguards (NMSS). Direct

² Under this option, the NRC and Agreement State would only accept board certifications from medical specialty boards whose certification processes have been recognized by the NRC or Agreement State as meeting NRC or Agreement State T&E requirements.

support is expected from MSST; OAS; NRC Region 3; and the Office of the General Counsel (OGC). The project sponsor for this activity is Kevin Williams, Director, NMSS/MSST.

This WG will operate as a joint NRC/OAS WG as described in NRC’s Management Directive 5.3 “Agreement State Participation in Working Groups” ([ML16083A204](#)) and in accordance with NMSS Procedure SA-801, “Agreement State Participation in NRC Working Groups” ([ML22245A083](#)). SA-801 details the procedure for NRC and Agreement State interactions during working group activities. The WG membership may change during the execution of the project and the WG may seek additional expertise on an as-needed basis. The WG may also designate a member of the ACMUI to serve as a WG member or advisor. The membership and responsibilities are depicted in the following table:

Organization	Working Group Members
NRC/NMSS/MSST	Cindy Flannery, Technical Lead Maryann Ayoade, Technical Expert Daniel Shaw, Technical Expert
NRC/Region 3	Elizabeth Tindle-Engelmann, Regional Representative
NRC/OGC	Ian Irvin, Attorney
OAS	Augustinus Ong, NH, Agreement State Representative

If the WG needs management support to resolve issues that are significant or have policy implications, then a Steering Committee would be convened for this effort. The Steering Committee Chair would be the Director or Deputy Director of MSST, and the members would include a regional Director of the Division of Radiological Safety and Security; the OGC Assistant General Counsel for Materials, Fuel Cycle, and Waste Programs; and the OAS Director of Rulemaking appointed by the OAS Executive Board/Director of Emerging Issues and Advocacy, or their designees.

ACTIVITIES AND SCHEDULE

The high-level schedule below covers the guidance development process. The schedule is preliminary and may change. A more detailed schedule will be provided to WG members.

WG Activities – guidance development	February 2023
<i>Kick-off meeting</i>	February 7, 2023
<i>Complete draft guidance</i>	October 2023
Division and Interoffice concurrence, Standing Committee on Compatibility review, QTE review	November – December 2023
90-day ACMUI and Agreement State review	January – March 2024
Meeting with ACMUI	March 2024
OGC No Legal Objection	April 2024
60-day public comment period	May – June 2024
Public meeting	May/June 2024
Disposition comments, develop CA note	July 2024
CA Note due to OEDO (8/20) and SECY (8/27)	August 20, 2024

LEVEL OF EFFORT

WG members should expect to provide commitment to this activity until the objectives are completed. The expected level of effort is 2-4 hours per week, which includes meetings weekly or as needed. Periodic briefings with interested managers on the WG activities may be held to solicit feedback and comments. The level of effort would be 1 hour per briefing.

The NRC WG members should charge time associated with the activities identified in this charter to CAC A34021, "NB-NMU-Licensing Support," with EPID M-2023-LIC-0000, "Part 35 T&E Implementation Guidance."

MEETINGS

The WG will maximize the use of electronic communications such as Microsoft Teams, SharePoint, and email to maximize interaction within the WG and among its members.



Clark, Theresa signing on behalf
of Williams, Kevin
- on 03/15/23

Kevin Williams, Director, NRC/NMSS/MSST



Steve Seeger, Chair, OAS

SUBJECT: CHARTER FOR THE U.S. NUCLEAR REGULATORY COMMISSION/
AGREEMENT STATE WORKING GROUP TO DEVELOP TRAINING AND
EXPERIENCE IMPLEMENTATION GUIDANCE. DATE: March 21, 2023

ML23082A024

OFFICE	NMSS/MSST	NMSS/MSST	NMSS/MSST	NMSS/MSST	OAS
NAME	CFlannery	CValentin-Rodriguez	CEinberg	TClark for KWilliams Director	SSeeger Chair
DATE	3/8/2023	3/9/2023	3/13/2023	3/15/2023	3/21/2023

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